

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMGEN INC. and AMGEN)	
MANUFACTURING, LIMITED,)	
)	C.A. No. 18-1064-CFC-CJB
Plaintiffs,)	
)	PUBLIC VERSION
v.)	
)	
HOSPIRA, INC. and PFIZER INC.,)	
)	
Defendants.)	

**AMGEN’S REPLY IN SUPPORT OF ITS MOTION TO STRIKE
PFIZER’S NEWLY-ASSERTED PRIOR-COMMERCIAL-USE
DEFENSE UNDER 35 U.S.C. § 273**

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Dated: August 10, 2021

The trial in this action is set for September 20, 2021. Yet Pfizer did not disclose its non-infringement theory under 35 U.S.C. § 273 until July 9, 2021 as a new contingent defense when it sent Amgen a draft of Pfizer's portion of the Pretrial Order (PTO).¹ This is undisputed. On this ground, Amgen's motion to strike may be granted because Amgen was not on notice of Pfizer's § 273 theory until the eve of trial. As this Court held in precluding a belated theory:

[The] mere disclosure of facts underlying an invalidity theory does not constitute a disclosure of the theory. The purpose of final invalidity contentions is to give fair notice to the patentee of the theories of invalidity the accused infringer will pursue at trial. Notice of the facts underlying those theories is insufficient.

**

Sandoz's disclosure of its inventorship theory on the eve of trial and almost eight months after it served its final contentions was unjustified, prejudiced Plaintiffs, and deprived Plaintiffs of the opportunity to cure any prejudice. Sandoz's explanation for its late disclosure is suspect, though I find it unnecessary to decide whether it acted in bad faith. The balance of relevant factors weighs in favor of Plaintiffs' request to preclude Sandoz from pursuing its Pharmorphix inventorship theory, and accordingly I will grant that request.

Pharmacyclics LLC v. Cipla Ltd., No. CV 18-192-CFC/CJB, 2020 WL 6581643, at *1, *3 (D. Del. Nov. 10, 2020). The same is true for Pfizer's new § 273 theory, which would severely prejudice Amgen if allowed. (*See* D.I. 299 at 7-13.)

¹ While Pfizer originally asserted a § 273 defense that was contingent upon the Court's grant of Amgen's motion for partial summary judgment (D.I. 300, Ex. A) (which the Court denied, D.I. 307), Pfizer has now changed its position. (Ex. H.)

Notably, neither party asserts that the September 20, 2021 trial should be delayed because of Pfizer's new theory. However, Pfizer wishes to go ahead and present the new defense at trial, arguing there would be no prejudice to Amgen because its § 273 theory is supposedly based on the "very same" facts underlying its "prior public knowledge and use [invalidity defense] under 35 U.S.C. § 102." (D.I. 303 at 1.) Amgen disagrees that the same facts underlie these defenses, as discussed below and in Amgen's opening motion. Here, Amgen was deprived of the opportunity—and had no reason—to take discovery on facts and issues that would rebut a § 273 theory as they were not relevant to Pfizer's other defenses and Amgen should not have to explore these facts for the first time at trial.

For example, a central issue under 35 U.S.C. § 273(e)(4) is whether the alleged commercial use was abandoned. During discovery, Pfizer's corporate witness provided evidence which strongly suggests abandonment because he testified that [REDACTED]

[REDACTED]

[REDACTED] (Ex. I at 29:6-17.) But Amgen did not pursue discovery from Teva on that issue, because it is not relevant to rebutting Pfizer's prior-knowledge-and-use defense. This illustrates the prejudice to Amgen.

Further, Pfizer never disclosed the grounds for its new theory in its non-infringement contentions, not even now. (D.I. 299 at 3; Ex. J at 14-24.) Where, as

here, Pfizer failed to provide such information, “the party is not allowed to use that information or witness to supply evidence ... at a trial, unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1). Pfizer cannot meet this standard.

A. Pfizer’s Failure to Disclose Its New § 273 Theory Is Unexplained and Not Substantially Justified

Pfizer does not justify its belated disclosure except to say that the “lapse was inadvertent and not in bad faith.” (D.I. 303 at 1.) As with its on-sale-bar, public-use, and prior-knowledge defenses, this is not a defense for which Pfizer lacked access to information that would have allowed it to plead such a defense. Indeed, Pfizer contends the defense is based on the same facts underlying its public-use and prior-knowledge defenses. (*Id.*)

Yet, to this day, Pfizer offers no explanation that would justify waiting until the July 2021 PTO exchange to disclose Pfizer’s new theory. The fact that Pfizer’s counsel apparently failed to appreciate a § 273 defense before then is not a cognizable justification that permits Pfizer to add a new theory to the case on the eve of trial.²

² This is not the first time that Pfizer’s counsel has apparently failed to recognize a defense in this action, to Amgen’s prejudice. Pfizer’s counsel was also unable to explain why it waited until after the close of discovery to disclose its on-sale-bar, public-use, and prior-knowledge defenses. (D.I. 300, Ex. G at 34:10-20.)

Pfizer falls back on the BPCIA and an alleged underlying public interest as a reason why Pfizer should be permitted to evade the Federal Rules and this Court's orders. Specifically, Pfizer argues that "[j]ustice and the public interest support denying Amgen's motion to strike and permitting Pfizer to assert a defense to infringement that, if successful, would serve the critical public interest in affordable access to pharmaceutical drugs that prolong and save lives." (D.I. 303 at 2.) This fails because the public interest is not a factor in whether Pfizer has a substantial justification for its own delay. And the public interest does not give Pfizer license to ambush Amgen on the eve of trial with a defense that should have been disclosed.³

In both of the cases that Pfizer cites—*Genentech, Inc. v. Immunex R.I. Corp.*, 395 F. Supp. 3d 357, 366 n.6 (D. Del. 2019) and *Genentech, Inc. v. Amgen Inc.*, No. CV 18-924-CFC, 2019 WL 3290167, at *3 n.7 (D. Del. July 18, 2019), *aff'd*, 796 F. App'x 726 (Fed. Cir. 2020)—the Court discussed public interest when assessing whether an injunction as to a biosimilar product was warranted. That is not the case here. Not only is this a motion to strike and not a motion for an

³ The factual premise of Pfizer's argument is also incorrect as there is already vigorous biosimilar competition in this market. Sandoz has been selling its biosimilar to Neupogen since 2015 and captured 38% of the market by early 2019. (D.I. 227-1, Ex. 1 at p. 79).

injunction, but Pfizer's biosimilar product has long been on the market and available to patients.⁴

B. Pfizer's Failure to Disclose Its New § 273 Theory Is Not Harmless

Permitting Pfizer to assert an unpled and undisclosed § 273 defense would severely prejudice Amgen. It is a distraction from Amgen's final preparations on the numerous claims and defenses to be tried to a jury in just a month. And Amgen was deprived of the opportunity and lacked motivation to seek relevant documents and testimony, and test the credibility of Pfizer's allegations, which Amgen should not have to do for the first time during trial. As discussed in Amgen's opening motion, the assertion of a § 273 defense raises a multitude of issues on which Amgen has not had the opportunity and lacked motivation to take

⁴ While not an issue to be decided by the Court for this motion, Pfizer's opposition raises concerns that Pfizer may argue the jury should find no infringement because an infringement finding would not further "[t]he policy interest in 'providing incentives for pioneering research and development of new biologics.'" (D.I. 303 at 2-3.) Should the parties have a dispute, Amgen may seek relief from the Court to preclude Pfizer from offering such argument and evidence under Federal Rules of Evidence 402 and 403. Infringement depends on a comparison of the patent claims and the accused process; there is no place for a weighing of competing public interest considerations. Permitting Pfizer to raise public interest arguments to the jury would unfairly prejudice Amgen, distract the jury, and cause confusion. *See, e.g., Abbott Lab'ys v. Sandoz, Inc.*, 743 F. Supp. 2d 762, 778 (N.D. Ill. 2010) ("[T]he Court will exclude as irrelevant and prejudicial any evidence or argument regarding the general benefits of generic drugs over branded drugs.").

discovery, including transfer of the personal defense through a chain of acquisitions, abandonment of commercial use, and the restriction on manufacturing sites. (D.I. 299 at 7-13.)

Pfizer spends more than 10 pages attempting to dispute whether Amgen had the opportunity to take discovery on a § 273 defense by arguing that the facts are undisputed and that information produced by Pfizer supports its new theory. (D.I. 303 at 6-16.) But this misses the point. The issue is not what evidence *Pfizer* plans to adduce at trial to support its new theory, or whether the facts presented by Pfizer without giving Amgen notice of a § 273 defense are undisputed. Instead, it is whether *Amgen* had the opportunity and motivation to take discovery on facts rebutting a § 273 defense. Amgen has been deprived of that opportunity and lacked such motivation as Amgen had *no reason* to explore numerous facts and issues that are relevant to a § 273 defense but are not relevant to Pfizer's other defenses. Where, as here, Amgen indisputably did not have notice of a § 273 defense, Amgen's alleged "broad discovery" of facts relating to the new theory is not tantamount to Amgen having notice of the theory and having the opportunity and motivation to take discovery of the specific facts relating to that theory. *See Pharmacyclics LLC*, 2020 WL 6581643, at *1-3.

In any event, Pfizer's assertion that Amgen has obtained discovery on "every topic relevant to Pfizer's Section 273 defense" is incorrect. (D.I. 303 at

16.) As Pfizer appears to concede, litigation of a § 273 defense would require resolution of disputed facts “related to the transfer of rights to Pliva’s filgrastim line of business, including any alleged abandonment thereof, and manufacturing sites” (D.I. 303 at 7; D.I. 299 at 10-11.) Yet Amgen was never put on notice of a need to take discovery on these issues, none of which is an element of Pfizer’s other defenses in this action.

First, with respect to whether the defense was validly transferred under § 273(e)(1)(A), at least four agreements would have been relevant had Pfizer pled and disclosed a § 273 defense: (1) a 2006 transaction involving Croatian company Pliva and U.S. company Barr; (2) a 2008 transaction involving Barr and Israeli company Teva; (3) a 2009 transaction involving Pliva (then part of Teva) and Defendant Hospira; and (4) a 2015 transaction involving Defendants Hospira and Pfizer. (D.I. 299 at 11 n.4.) But Amgen had no reason to pursue discovery as to these agreements because Pfizer’s counsel represented to the Court that its invalidity defense relied solely on a wholly separate agreement (the 2005 DSM Agreement): “those subsequent events are not relevant to the invalidity defense. The question is at the time of the sale, and the sale we’re relying on is the 2005 agreement where Bar[r], were Bar[r] and Pliva, separate companies, and they were, and this was an arm’s length transaction.” (D.I. 300, Ex. G at 37.) And Pfizer has not produced all of these agreements: Pfizer’s opposition attaches only one of

those agreements (the 2009 Pliva and Hospira agreement (D.I. 304-1, Ex. B.)) because the others were never produced in discovery. Further, Pfizer refused to provide a corporate witness to testify as to “[a]ll transaction(s) relied upon by [Pfizer] to assert invalidity under 35 U.S.C. §102(b).” (Ex. K at 12.) Instead, Pfizer offered a corporate witness to testify only as to the 2005 DSM Agreement. (*Id.* at 12-13.)

Second, with respect to abandonment under § 273(e)(4), Pfizer’s entitlement to this defense depends on the continuity of the alleged commercial use by the entities involved in the four transactions. Even though Amgen obtained some discovery related to abandonment—including [REDACTED] [REDACTED] discussed above—Amgen had no motivation to pursue further discovery on abandonment because it is not relevant to Pfizer’s other defenses. Pfizer does not dispute this. Instead, Pfizer argues that Amgen was not prejudiced, because Pfizer has produced some information that supports its claim of no abandonment. (D.I. 303 at 14-15.) But disclosure of facts underlying a theory is not the same as disclosure of a theory. *Pharmacyclics*, 2020 WL 6581643 at *1, *3. And resolution of this motion to strike does not depend on whether Pfizer’s new defense can succeed based on the evidence Pfizer has produced. Setting forth merits arguments in opposition to a motion to strike does not eliminate the prejudice to Amgen: because Pfizer has never provided contentions for its new

theory, Amgen could not and did not test the credibility of, and seek discovery on, facts rebutting any such contentions.

Further, as with the agreements relevant to the transfer issue, Pfizer refused to provide discovery on facts relevant to abandonment. For example, Pfizer relies on the accused process being “almost identical” to the Pliva-Barr alleged process (D.I. 303 at 14), even though Pfizer’s regulatory submissions do not rely on Pliva-Barr’s regulatory submissions as would be expected if the processes were the same. And during discovery, Pfizer refused to provide a corporate witness to testify on the reason why [REDACTED] [REDACTED]. (Ex. K at 34-35.)

Third, with respect to the manufacturing location issue under § 273(e)(1)(C), the parties would have had a factual dispute regarding whether Pfizer’s accused process was in use at its current site before the date of transfer of Pliva’s line of business, had Pfizer pled and disclosed a § 273 defense. Pfizer’s assertion that it has provided information on its current manufacturing site is beside the point. (D.I. 303 at 15-16.) Amgen did not take (and had no motivation to take) discovery on how long the accused process was in use at its current site. That Pfizer’s aBLA identifies its current manufacturing site is not the same as providing discovery on the historical use of the accused process at that site before Hospira allegedly acquired the line of business on September 30, 2009. For

example, Pfizer cites to Dr. Valinger's testimony that [REDACTED] (D.I. 303 at 16.) If the accused process were transferred to its current site in 2010 after the September 2009 Hospira-Teva transaction (as appears to be the case, Ex. L at HOS-FILG-00004641), then the accused process would not have been in use at its current site before the date of the alleged business-line transfer to Hospira as required by § 273(e)(1)(C). This highlights the prejudice to Amgen: because Amgen did not have notice of a § 273 defense, Amgen was not motivated to and did not pursue additional discovery.

Accordingly, Amgen respectfully requests that the Court strike Pfizer's newly-asserted § 273 defense to infringement, including from Pfizer's pretrial exchanges and its trial presentation, and impose any other appropriate sanctions.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 10, 2021, a true and correct copy of the foregoing document was filed with the Clerk of Court via CM/ECF which will send notification of such filing to counsel of record and I further certify that a true and correct copy of the foregoing document was caused to be served on the following counsel as indicated:

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

The undersigned attorney certifies that the forgoing brief complies with the type-volume limitations set forth in the Scheduling Order (D.I. 26). The text of this motion has been prepared in Times New Roman, 14 point font. As determined by Microsoft Word, the text of this opposition contains 2,500 words, excluding the case caption.

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